

# PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115

**DRAFT**

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**Created by:**



**Center for Medicaid and State Operations**

NOTE: This application template is pending approval from the Office of Management and Budget and is considered draft.

# PHARMACY PLUS

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# PHARMACY PLUS

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### Purpose and Application Instructions

#### **Purpose:**

- Remove barriers to pharmacy coverage for low-income Medicare beneficiaries who are age 65 or older or who have a disability, whether or not they are eligible for Medicare Savings programs under Medicaid [which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g., Qualified Medicare Beneficiaries (QMBs) and Specified Low-income Medicare Beneficiaries (SLMBs)] who have not been determined eligible for full Medicaid benefits. Low-income is defined as having income at or below 200 percent of the federal poverty level (FPL).
- Promote flexibility for states that seek to provide pharmacy coverage.
- Reduce the administrative burden on states by providing a streamlined demonstration application.
- Provide guidance on key program design, cost containment, and budget requirements, such as:
  - benefit package
  - use of private sector pharmacy benefit management approaches
  - cost sharing
  - coordination with private insurance payers
  - data and budget worksheets needed to assure budget neutrality
- Increase the speed of the federal review.

#### **Features:**

- Electronic application format with pop-up instructions for easier submission of essential program information.
- Structured series of check-off options to be selected by the states.
- Simplified submission of data using an Excel template.
- Model special terms and conditions of approval that support pharmacy expansions.

#### **Application Submission Instructions:**

This application has been written to read as a document prepared by the applicant including

assurances to CMS by the applicant. The Pharmacy Plus Demonstration Template is a check-off application to guide and streamline the application process. Applicants should complete the check-off application and the budget shell and submit these items to CMS. The items within a shaded box are instructions to the user, and should be deleted prior to submission (with the exception of the “Pharmacy Plus” title). The sample Special Terms and Conditions of Approval document should be excluded. We recommend that the applicant complete the check-off application in conjunction with technical assistance from CMS Central Office and Regional Office staff.

1) mail hard copy original to:

Deirdre Duzor/Larry Reed,  
Pharmacy Team  
Center for Medicaid and State Operations  
Centers for Medicare & Medicaid Services  
Mailstop S2-08-07  
7500 Security Blvd  
Baltimore, MD 21244  
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2) e-mail to:

[PharmacyPlus@cms.hhs.gov](mailto:PharmacyPlus@cms.hhs.gov)

The creation of this template has been through a team effort from the Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations. Any questions relating to the template may be directed to (410) 786-4626. In the voicemail, leave a detailed message with your name, organization, phone number (with area code), e-mail address, and the type of information you would like to receive.

# PHARMACY PLUS

## A DEMONSTRATION PROGRAM UNDER SECTION 1115

### Pharmacy Plus Application

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**The State of Delaware , Department of Health and Social Services proposes an 1115 Demonstration Proposal entitled Delaware Pharmacy Assistance Program, which will extend pharmacy services and related medical management interventions to aged and disabled individuals at or below 200% percent of the federal poverty level (FPL).**

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#### I. GENERAL DESCRIPTION

This demonstration will extend pharmacy coverage to individuals in a fashion that furthers public, private, and individual fiscal responsibility. The demonstration is designed to assist low-income Medicare beneficiaries who have high drug costs. The demonstration offers assistance by 1) providing access to prescription drugs and related services, 2) assisting individuals with high premiums/cost sharing for private coverage for prescription drugs, or 3) providing [wraparound](#) pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage. The proposed program also ensures access to primary care to complement and assist in the management of the enrollee's pharmacy services. An important element in Pharmacy Plus is the use of competitive private sector approaches, such as benefit management, to provide more cost effective, modern prescription drug benefits in Medicaid

Individuals eligible for the proposed program include those who are Medicare beneficiaries, who have not been determined eligible for [full Medicaid](#) benefits, whether or not they are eligible for Medicare Savings programs under Medicaid (which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g., QMBs and SLMBs) and/or people with a disability. Cost sharing - in the form of premiums, copayments, coinsurance, and deductibles - for the expansion population may differ from cost-sharing requirements for the regular Medicaid program.

The [budget neutrality](#) ceiling will be a single aggregate budget amount for the demonstration period. The state will be accountable for both expenditure and enrollment growth in the population subject to the budget neutrality ceiling which includes both the demonstration enrollees and the budget neutrality [impacted population](#).

The demonstration will operate for five years, beginning approximately July 1, 2003.

## II. ASSURANCES

Each of the following items are checked to indicate an assurance:

- A. X **Primary care coordination.** The demonstration includes a mechanism to direct demonstration enrollees who access services to sources of primary health services. Such primary care will include, but is not limited to, medical management related to prescription and non-prescription pharmaceutical products. The state assures that those individuals who do not have access to primary care as Medicare beneficiaries will have access to primary care services. More information about this requirement is provided in [Section V, Part I](#).
- B. X **Benefits, access to services, and cost sharing.** The benefits and rights of the State Plan eligibility groups, except for restriction to choice of providers as provided through a section 1115(a)(1) waiver of 1902(a)(23) through Pharmacy Plus, are as provided for in the state's Medicaid State Plan, Title 42 of the Code of Federal Regulations, and Title XIX of the Social Security Act.
- C. X **Budget neutrality.** The federal cost of services provided during the demonstration will be no more than 100 percent of the expected federal cost to provide Medicaid services under current law without the demonstration. The benefits and rights of the State Plan eligibility groups are not altered by this demonstration. An Excel budget worksheet is provided that includes the budget projections, with and without waiver cost estimates, information about covered individuals, trend rate information, and a narrative description of the calculations. More information about this requirement is provided in [Section VI](#).
- D. X **Public notice requirements.** The demonstration complies with public notice requirements as published in the Federal Register, Vol. 59, No. 186 dated September 29, 1994 (Document number 94-23960) and Centers for Medicare & Medicaid Service (CMS) requirements regarding Native American Tribe consultation. Provide information about this assurance in [Appendix 1](#).

### III. STATE-ONLY FUNDED PHARMACY PROGRAMS

The following information is provided for current state-only funded pharmacy programs (Check all that apply):

A. X **State Program Entirely Subsumed Into Demonstration.** A state-only funded pharmacy program named Delaware Prescription Assistance Program (DPAP) currently exists, and it will be subsumed by the demonstration (Complete this section for each state program that will be entirely subsumed into the demonstration program. Provide as an attachment a description of the state-only funded program, including enrollee cost-sharing, benefit limits, wraparound coverage, and any other pertinent features).

1. Income level ceiling. The income level ceiling for participation is 200 percent FPL.
2. Program eligibility characteristics. In addition to income ceiling, the program eligibility parameters have the following further specifications:
  - a. X age group (describe): 65 years of age or older
  - b. X condition specifications (describe): between the ages of 19 and 64 and eligible for benefits under Title II of the Social Security Act
  - c. \_\_\_\_\_ other specifications (describe):
3. Benefit coverage scope. The scope of benefits covered under the program is
  - a. X broad (such as the Medicaid package)
  - b. \_\_\_\_\_ narrow (such as limited to drugs to treat specific health conditions)
  - c. \_\_\_\_\_ other (describe):
3. X There are enrollee financial contributions, which include:
  - a. \_\_\_\_\_ premiums (describe):
  - b. \_\_\_\_\_ deductibles (describe):
  - c. X copayments/coinsurance (describe): \$5 or 25% of the cost, whichever is greater
  - d. \_\_\_\_\_ other (describe):
4. X This proposed demonstration will be an expansion of coverage compared to the current state pharmacy program through:
  - a. \_\_\_\_\_ expanding the scope of coverage (e.g., type or number of prescriptions available)
  - b. X expanding the pharmacy services available (e.g., by providing a pharmacy or nurse consultant who will provide additional management services)
  - c. \_\_\_\_\_ expanding the type of individuals eligible
  - d. \_\_\_\_\_ expanding the number of individuals eligible
  - e. \_\_\_\_\_ expanding funding to assist with premiums and cost sharing
  - f. \_\_\_\_\_ other (describe)
5. Annual cost. Currently the program expenditures are \$ 5,242,213 on an annual basis for the program.

6. Enrollment figures. Currently there are 4,845\* enrollees in the program. (Average during SFY 02)
7. X This proposed demonstration will not be an expansion of coverage compared to the current state pharmacy program, but enactment of pharmacy cost-saving measures in Medicaid will assist to achieve budget neutrality.

**B.        State Program Partially Subsumed Into Demonstration.** A state-only

C. funded pharmacy program named                      currently exists, and will be **partially** subsumed by the demonstration (Complete this section for each state program that will be partially subsumed into the demonstration program. Provide as an attachment a description of the state-only funded program, including enrollee cost-sharing, benefit limits, wraparound coverage, and any other pertinent features).

1. Income level ceiling. The income level ceiling for participation is            percent FPL.
2. Program eligibility characteristics. In addition to income ceiling, the program eligibility parameters have the following further specifications:
  - a.        age group (describe):
  - b.        condition specifications (describe):
  - c.        other specifications (describe):
3. Benefit coverage scope. The scope of benefits covered under the program is
  - a.        broad (such as the Medicaid package)
  - b.        narrow (such as limited to drugs to treat specific health conditions)
  - c.        other (describe):
4.        There are enrollee financial contributions, which include:
  - a.        premiums (describe):
  - b.        deductibles (describe):
  - c.        copayments/coinsurance (describe):
  - d.        other (describe):
5.        This proposed demonstration will be an expansion of coverage compared to the current state pharmacy program through:
  - a.        expanding the scope of coverage (e.g., type or number of prescriptions available)
  - b.        expanding the pharmacy services available (e.g., by providing a pharmacy or nurse consultant who will provide additional management services)
  - c.        expanding the type of individuals eligible
  - d.        expanding the number of individuals eligible
  - e.        expanding funding to assist with premiums and cost sharing
  - f.        other (describe)

6. Annual cost. Currently the program expenditures are \$ \_\_\_\_\_ on an annual basis for the program.
7. Enrollment figures. Currently there are \_\_\_\_\_ enrollees in the program.
8. \_\_\_\_\_ This proposed demonstration will not be an expansion of coverage compared to the current state pharmacy program, but enactment of pharmacy cost-saving measures in Medicaid will assist to achieve budget neutrality.

C. \_\_\_\_\_ **State Program Not Subsumed by Demonstration.** A state-only funded pharmacy program(s) named \_\_\_\_\_ currently exists, will not be subsumed by the demonstration, and will continue to operate during the Pharmacy Plus demonstration operation.

D. \_\_\_\_\_ **No State Funded Pharmacy Program Currently Exists.** A state-only funded pharmacy program does not exist in this state.

## IV. PROGRAM ELEMENTS

### Population to Whom Eligibility is Expanded under this Demonstration

Individuals eligible for Pharmacy Plus include those who are Medicare beneficiaries, whether or not they are eligible for Medicare Savings programs under Medicaid (which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g., QMBs and SLMBs) and/or people with a disability, who have not been determined eligible for full Medicaid benefits. States may also propose to extend the pharmacy benefit to persons age 65 and older who are not Medicare beneficiaries and to persons under age 65 who receive Social Security Disability Insurance (SSDI) but not Medicare (i.e., are in the 24-month waiting period for Medicare) or who have a disability as defined by the Supplemental Security Income program.

#### A. Eligibility Groups

1.   X   Aged individuals (65 and older)
  - a.   X   Medicare beneficiaries
  - b.   X   non-Medicare beneficiaries
  - c.        individuals with private pharmacy coverage (describe):
  - d.        other (describe):
2.   X   Individuals with Disabilities (ages   19   to   64   )
  - a.   X   Medicare beneficiaries
  - b.        individuals with private pharmacy coverage (describe):
  - c.   X   Social Security Disability Insurance (SSDI) beneficiaries in 24-month waiting period for Medicare
  - d.        lost SSDI due to earnings (disabling condition continues)
  - e.        could receive Supplemental Security Income if federal eligibility rules used (for 209(b) states)
  - f.        other (describe):
3.   X   Other (describe): Aged or Disabled with income above 200% FPL who have prescriptions that exceed 40% of countable income.

#### B. Income Groups

1.   200   percent of FPL is the ceiling for the demonstration expansion group for aged individuals. NOTE, the CMS proposed ceiling is 200 percent FPL or below. The current Medicaid State Plan coverage percentage level for this group is   75   percent FPL for SSI recipients(if group varies within the aged population, describe): 250% of SSI for individuals in nursing facilities and Home and Community Based Services waivers
- 200   percent of FPL is the ceiling for the demonstration expansion group for individuals with disabilities. NOTE, the CMS proposed ceiling is 200 percent FPL or below. The current Medicaid State Plan coverage percentage level for this group is   75

\_\_\_\_ percent FPL for SSI recipients (if group varies within the disabled population, describe) 250% of SSI for individuals in nursing facilities and Home and Community Based Services waivers

3. Aged or Disabled with income above 200% FPL who have prescriptions that exceed 40% of countable income.

### **C. Income Adjustments**

1. \_\_\_\_ Income is adjusted
  - a. \_\_\_\_ in the same manner as in Medicaid for the \_\_\_\_ group
  - b. X in a different manner than in Medicaid (describe): See Attachment 4
2. \_\_\_\_ income is not adjusted

### **D. Assets Test**

1. \_\_\_\_ an assets test will apply. It is
  - a. \_\_\_\_ the same as the Medicaid assets test for the \_\_\_\_ group
  - b. \_\_\_\_ different from the Medicaid assets test (describe)
2. X no assets test will apply

### **E. Enrollment Limit**

1. \_\_\_\_ is the total number of demonstration enrollees permitted to enroll in the demonstration (describe how and why this number was chosen):
2. \_\_\_\_ There will not be an enrollment ceiling
3. \_\_\_\_ The state will not utilize an enrollment ceiling initially, but will track budget neutrality and plans to utilize the enrollment ceiling at a later point in time (describe): Program enrollment and expenditures are based on budget forecasts and will be monitored throughout the period. The purpose of the enrollment cap is to ensure that the State has sufficient funds to cover the costs associated with the program. State costs under the waiver will be limited to expenditures appropriated by the State legislature. (See Attachment 7)

### **F. Pharmacy Benefits Package**

Consistent with the pharmaceutical focus of Pharmacy Plus, the demonstration does not include non-pharmacy benefit changes (such as reducing Medicaid coverage for other services or reducing coverage for existing Medicaid populations). The challenge posed in Pharmacy Plus is to improve cost-effectiveness through maintaining the health status of individuals and managing medications more effectively. The drug rebate provisions of section 1927 of the Social Security Act are triggered by state payments for prescription drugs under the plan by operation of the Pharmacy Plus demonstration project, and thus, [rebates](#) may be collected from manufacturers for drugs provided to the expansion population. The federal share of rebates paid will be returned to the federal government.

The following describes the proposed benefits to be included in this demonstration (check all that apply):

1. ☐ demonstration eligibility will be extended to those who have pharmacy coverage through private health insurance, and enrollees will receive:
  - a. ☐ assistance with [private health insurance](#) cost sharing (see Section V.H.):
  - b. ☐ [wraparound](#) services (See Section V.H.):
  - c. ☐ other (describe and See Section V.H.):
2. ☒ enrollees without private health insurance pharmacy coverage will receive prescription drug coverage as follows:
  - a. ☒ the benefit package will be the same as in the Medicaid State Plan for non-demonstration enrollees
  - b. ☐ the benefit package will differ from that in the Medicaid State Plan for non-demonstration enrollees in that:
    - i. ☐ certain classes of drugs will be excluded or limited (describe):
    - ii. ☐ the number or frequency of prescriptions covered will be less than in the Medicaid State Plan for non-demonstration enrollees (describe):
    - iii. ☐ drugs covered only for specified conditions (describe):
    - iv. ☐ other (describe): a \$2,500 per year benefit limit, described under number 3, below
  - c. ☐ other (describe):
3. the state limits benefits to a financial ceiling per State fiscal year of \$ 2,500 (describe): The program provides up to \$2,500 per person, per State fiscal year (July 1 to June 30) for prescription assistance.
4. ☐ other (describe):

## **G. Pharmacy Benefit Management**

Pharmacy Plus programs may use private-sector benefit management approaches consistent with the requirements of section 1927(d) (such as pharmacy benefit managers, preferred drug lists, prior authorization, pharmacist consultation, provider education, disease state management, and variable enrollee cost sharing) in order to more efficiently and effectively manage pharmaceutical costs and ensure that spending stays within the federal budget neutrality cap. These benefit management approaches may also be extended to some or all of the existing Medicaid population, and the resulting savings used to achieve budget neutrality. The demonstration will include pharmacy benefit management as follows:

1. ☒ pharmacy benefit manager (describe): The Division of Social Services contracts with a fiscal agent (EDS) to conduct outreach, manage the application process, determine eligibility, and pay the prescription drug claims submitted from participating pharmacies.
  - a. ☐ this is currently used in the state Medicaid program, will continue to be operated similarly, and it is currently under contract with ☐.
  - b. ☒ this is not used in the Medicaid program and will be used only for

- demonstration enrollees.
- c. ☐ this will be introduced with the demonstration and will apply to the entire Medicaid population (demonstration and non-demonstration)
  - d. ☐ other (describe):
2. ☒ prior authorization (describe): Some classes of drugs will be authorized only after specific conditions have been met. In addition, drugs are placed on a prior request basis if they are deemed to have potential for abuse or misuse.
- a. ☒ this is currently used in the state Medicaid program
  - b. ☐ this is not used in the Medicaid program and will be used only for demonstration enrollees
  - c. ☐ this will be introduced with the demonstration and will apply to the entire Medicaid population (demonstration and non-demonstration)
3. ☐ N/A formulary or formulary exclusions consistent with Section 1927(d)(4) of the Social Security Act (describe):
- a. ☐ this is currently used in the state Medicaid program
  - b. ☐ this is not used in the Medicaid program and will be used only for demonstration enrollees
  - c. ☐ this will be introduced as a State Plan Amendment with the demonstration and will apply to the entire Medicaid population (demonstration and non-demonstration)
4. ☒ other (describe)
- a. Step Therapy - Step-therapy is a prescription pattern based on the stage of illness; the drug believed to be the most cost-effective is used first, followed by more expensive therapies. Applying this concept to pharmaceuticals entails evaluation of the daily cost of a medication, as well as the associated laboratory work and potential for side effects or adverse reactions related to each medication that would be appropriate. Several examples describe the purpose of using step therapy:
    - Non-selective antihistamines are equally as effective as the non-sedating antihistamine agents. The non-selective medications can be twenty times more expensive per day. If the client is not affected by the sedative effect of the non-selective medicine then the older, less expensive agent should be attempted first.
    - Medications used to treat pain associated with swelling have many agents. The older agents are equally as effective as the newer agents. They are much cheaper since they are available generically. The newer agents should be reserved for the clients who have either demonstrated an adverse reaction to the older agent or have a preexisting condition that warrants using the newer agents.

Applying step therapy as a means of guiding prescribing habit is an effective way of controlling cost without sacrificing benefits or quality of care. EDS estimates

that prescription costs for the Medicaid program will decrease by 5% after step therapy is implemented.

- b. Retrospective DUR - Duplicate Therapies - An ongoing review of pharmacy claims indicates that 3% of all Medicaid prescriptions are duplicate therapies that occur in spite of the prospective DUR procedures. In these cases, pharmacists override the system's recommendations.
- c. Prospective DUR - Overutilization - Overutilization (early refills) typically represent the highest number of clinical alerts for pharmacists at the Point of Service (POS). EDS estimates that the number of prescriptions that would not be filled as the result of overutilization could be increased by 25% per year.

## **H. Coordination with Other Sources of Pharmacy Coverage – Private, State, and Medicare Plus Choice Plans**

Coordination with and non-duplication of existing sources of health insurance is an important feature of the Pharmacy Plus Demonstration. It maintains the position of Medicaid as payer of last resort and provides an incentive for enrollees to continue to participate in private coverage, thus supporting the maximization of participation in [private insurance](#), employer sponsored insurance, COBRA, retiree health insurance plans, Medigap plans and Medicare+Choice plans. Pharmacy Plus is designed to work effectively with other Medicare pharmacy options.

The coordination and support can be:

- Actuarially equivalent payments to private carriers (or to enrollees) made on behalf of Pharmacy Plus in lieu of direct coverage of pharmaceuticals under the Pharmacy Plus program; and/or
- In the form of providing wraparound pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage.

In this demonstration, the following approaches will apply (check all items that apply – Also, See Section V.F.1.):

1. \_\_\_\_ Subsidies/cost sharing assistance for private health insurance coverage will be provided under the demonstration, and is clarified in the submitted budget neutrality information. The process for providing the subsidy will be described in the operational protocol and CMS approval of the payment methodology and amount will be requested. Subsidies/incentives will be provided for enrollees to maintain coverage of the following:
  - a. \_\_\_\_ Private health insurance coverage (describe):
  - b. \_\_\_\_ Medigap (describe):
  - c. \_\_\_\_ Medicare-endorsed pharmacy discount cards. The demonstration includes financial contribution towards the drugs purchased using the card (describe coordination with the card and contribution to the purchase)

- d. \_\_\_\_\_ other (describe)
2. \_\_\_\_\_ Pharmacy coverage will be provided to enhance other sources of pharmacy coverage, such as state programs, Medicare+Choice and private sources of coverage in a wraparound fashion in order to encourage participation in existing public and private sources of care (describe):
3. \_\_\_\_\_ Other (describe):
4. \_\_\_\_\_ Third Party Liability will be collected in the demonstration in the following manner (describe):
5. X Third Party Liability will not be collected in the demonstration because
- a. X individuals with other pharmacy coverage are excluded
- b. \_\_\_\_\_ other (describe):
- X Coordination with other sources of coverage is not part of this demonstration because: The program eligibility criteria will ensure that eligible applicants do not have another form of prescription insurance.

**I. Primary Care Coverage and Related Medical Management (check all that apply)**

The demonstration includes a mechanism to ensure that demonstration enrollees have access to primary care health services that will assist with medical management related to pharmacy products prescribed. These aspects of the demonstration will be implemented as follows:

1. X Demonstration enrollees who have a source of coverage for primary care (for example, Medicare coverage) will use their primary care providers to coordinate the pharmacy benefit (describe): Enrollees will continue to depend upon their family physicians to oversee their primary health care services.
2. X Demonstration enrollees who do not have a source of primary care coverage will receive primary care services through the demonstration as follows:
- a. \_\_\_\_\_ A primary care benefit the same as that in Medicaid will be provided (describe):
- b. \_\_\_\_\_ A limited primary care benefit of \_\_\_\_\_ number of visits per \_\_\_\_\_, which entail the following services will be provided by \_\_\_\_\_ practitioners: \_\_\_\_\_.
- c. X Primary care access will be ensured by connecting clients to primary care sources for care in the community (e.g., FQHCs/RHCs, Ryan White providers, Indian Health Services facilities, Veterans' Affairs clinics, etc.) If the above is checked, the following must be checked and completed:

- i.   X   state to work with Primary Care Associations to facilitate access to services

The Delaware Healthcare Commission sponsors the Delaware Community Healthcare Access Program (CHAP). CHAP provides low cost or no cost primary care "medical homes" to individuals who are ineligible for the Diamond State Health Plan (Medicaid Managed Care) or the Delaware Healthy Children Program, yet who have incomes within established income limits. Enrollment in CHAP also provides eligible individuals with access to a statewide network of medical subspecialty services.

CHAP patients' eligibility is identified by the Delaware Division of Social Services and/or "Care Coordinators" located at one of twelve locations throughout the state. Care Coordinators assist individuals in applying to insurance programs, and depending upon financial eligibility provide linkage for clients to physician resources that comprise the CHAP provider network. The CHAP provider network consists of federally qualified health centers in each of Delaware's counties and the Voluntary Initiative Program Phase II (VIP II), a formal network of private practice physicians coordinated by the Medical Society of Delaware.

There are currently three federally qualified community health centers in Delaware and a fourth is working towards its accreditation. The community health centers serve more than 10,000 patients each year.

The VIP II is also an integral component of CHAP and one of the primary sources of medical homes for CHAP enrollees. The VIP II is a formal network that assigns patients to physician's practices. The daily operation of the VIP II is carried out by a registered nurse that serves as a liaison between patient and physician office staff for initial appointment scheduling. The VIP II nurse coordinator is also the single point of contact for physician's staff to request medical subspecialty services for CHAP patients.

Based on current experience, it is anticipated that most clients will have a primary care physician. Those who do not will be referred to a FQHC or the VIP II program.

The VIP II Care Coordinator will administer an intake tool that captures demographic information and baseline health status information. Upon completion, the VIP II Care Coordinator will facilitate communication between the patient and the VIP II physician office for a scheduled appointment.

- ii.   X   geographic breakdown of FQHC services provided that demonstrates adequate capacity to serve the demonstration population

- iii.   X   pharmacy and state written materials for demonstration participants include names, locations, and phone numbers of community sources of primary care

CHAP brochures will be distributed to participating pharmacies.

- iv.        oral counseling by pharmacists to include information on accessing primary care
- v.        Other (describe)

3.        Other (describe):

**J. Premiums and Cost Sharing Information (check all that apply)**

Flexibility to include cost sharing, similar to that found in employer sponsored private health insurance coverage, is an important feature of the Pharmacy Plus Demonstration. Enrollee cost sharing can be in the form of annual or monthly premium assessments, per-prescription copayment requirements, coinsurance, deductibles, and coverage limits. Cost sharing helps the state to operate a budget neutral program and encourages personal responsibility and involvement of enrollees in their health care. States may require that cost sharing be met by demonstration participants (i.e., those in the [expansion population](#)) in order to receive benefits under the program. Cost sharing may be used to reduce program costs by requiring enrollee payments. To encourage the use of generic drugs and to discourage the use of costly drugs for which there are lower cost alternatives, Pharmacy Plus encourages states to use a three-tier system of copayments. Cost sharing models used in Pharmacy Plus may be designed to protect people with most severe illnesses or disabilities by offering “stop-loss” protection against the cumulative impact of copayments and deductibles

- 1.   X   The proposed program will include enrollee cost sharing (enrollment fees, premiums, copayments, coinsurance, deductibles, etc.):
  - a.        Enrollment fees will be required and are        every enrollment period of        months. If the fees vary according to individual FPL, specify below (describe):
  - b.        Premiums will be required:
    - i.        Premiums are tiered or charged according to a sliding fee schedule that is        attached or        described below:
    - ii.        Premiums are fixed in the amount of \$        per person on a        monthly basis,        annual basis, or        other (described):
    - iii.        Other (describe):
  - c.   X   Copayments and Coinsurance:
    - i.   the greater of \$5 or 25% of the cost   per prescription or
    - ii.        Beneficiaries will have different co-payments for single source, branded multi source, and generic drugs, according to the following schedule

(describe):

- iii. Brand name: \$ \_\_\_\_ per prescription or \_\_\_\_ percent of the cost.
- iv. Branded multi-source: \$ \_\_\_\_ per prescription or \_\_\_\_ percent of the cost.
- v. Generic: \$ \_\_\_\_ per prescription or \_\_\_\_ percent of the cost.

d. \_\_\_\_ Deductibles (describe):

e.  X  Cost sharing requirements will vary with utilization (i.e., premiums, copayments, and coinsurance)

i. \_\_\_\_ Cost sharing amounts/requirements will decrease as individuals use more services (describe):

ii.  X  Cost sharing amounts/requirements will increase as individuals use more services (describe): There will be a \$2,500 annual limit on the prescription benefit.

iii. \_\_\_\_ Other (describe):

2. \_\_\_\_ The proposed program will not include enrollee cost sharing that differs from that in the Medicaid State Plan

3. \_\_\_\_ The proposed program will include enrollee cost sharing stop-loss protections (describe):

4. \_\_\_\_ Other (describe):

**K. The Demonstration Will Deliver Services in the Following Manner** (check all that apply)

1. \_\_\_\_ Services will be delivered through private health insurance coverage

2.  X  Services will be delivered fee-for-service through this demonstration

3. \_\_\_\_ Services will be delivered through a system other than fee-for-service through this demonstration (describe):

4.  X  Services will be delivered through this demonstration using the same network of providers that deliver comparable services to Medicaid beneficiaries

5. \_\_\_\_ Services will be delivered through this demonstration using a subset of providers that deliver services to Medicaid beneficiaries

6. \_\_\_\_ Services will not be delivered by providers that serve Medicaid beneficiaries (describe how providers will be selected)

7. \_\_\_\_ Other (describe):

## V. BUDGET NEUTRALITY

The federal costs of services provided during the demonstration will be no more than 100 percent of the expected costs of providing Medicaid services without the demonstration. A new population that would otherwise not be eligible for Medicaid will be able to obtain prescription drugs paid for by Medicaid. While the demonstration includes individuals who are not otherwise eligible for full Medicaid coverage, this new population could become eligible for full Medicaid coverage over the life of the demonstration through deterioration in their health status and reduced income due to high medical expenses. Federal payments will be provided for the Pharmacy Plus costs incurred for the demonstration population to the extent that federal Medicaid payments to the state do not exceed what would otherwise be paid.

The groups subject to budget neutrality - called the impacted population - are those expected to generate savings for the state because participants in Pharmacy Plus will incur less costs and remain healthier, thereby creating a delay in the need for full benefit Medicaid, in effect, a diversion from eligibility. While the expenditures for these groups are included in budget neutrality, the benefits of the existing Medicaid eligibility groups are not to be altered. Cutbacks in eligibility for existing Medicaid eligibility groups covered under the state's Medicaid Plan cannot be used as a source of savings for purposes of meeting budget neutrality. Savings that do not reduce benefits or limit eligibility but are achieved through better management of pharmacy services to existing Medicaid populations may be considered in the budget neutrality calculations.

The [Terms and Conditions of Approval](#) will specify that demonstrations must be in compliance with federal law and regulation related to sources and uses of Medicaid financing. In its budget neutrality calculations, the state should be able to demonstrate the impact of any recent changes to Medicaid law and regulation in its without-waiver and with-waiver calculations. For example, a state with an approved Upper Payment Limit plan, entitled to a transition period, under regulation, must demonstrate how the excess payments made under the UPL plan will be phased out during the waiver.

The Terms and Conditions of Approval will specify the aggregate financial ceiling for future expenditures for which federal financial participation (FFP) will be available. Under the aggregate ceiling methodology the state and federal authorities must reach agreement prior to demonstration approval on cost and eligibility trend rates. The trend rates will then be in place in the budget ceiling during the demonstration.

The attached budget shell relies upon a credible methodology that estimates a budget neutral program. When a Pharmacy Plus demonstration entirely or partially subsumes a state-only funded pharmacy program, the state must provide documentation as to how Medicaid expenditures will be reduced under the demonstration (compared to the "without demonstration" levels) and how budget neutrality will be achieved. The attached budget shell X was used in the development of the [budget neutrality ceiling](#).

- A. Impacted Budget Neutrality Population.** Table V.1 identifies the Medicaid population groups that are included in the budget neutrality calculation (i.e., the impacted population).

Table V.1 (check all groups that apply):				
Population	All (1)	Institutionalized (2)	Community Dwelling (3)	Other (described): (4)
Aged	X			
Blind/Disabled Adults	X			
Blind/Disabled non-Adults				

- B. Costs.** The state estimates the services cost of this program will be \$ 46,077,645 over its five year demonstration period.

Refer to attached Excel spreadsheet for details.

This demonstration is designed to provide a pharmacy benefit to a population that currently does not have Medicaid and include those who are currently participating in the State operated Delaware Pharmacy Assistance Program. The pharmacy benefits in the Medicaid program and DPAP have been subject to well-established pharmacy management procedures for several years. Some of the savings from these procedures have been realized. Nevertheless, we expect the Demonstration project to be budget neutral by applying some new cost-saving procedures.

The budget templates present data on the four population groups where savings would be realized:

- The DPAP (expansion) population - This includes participants in the current DPAP program and those covered through the expansion of the program.
- The institutional population - This represents the segment of the population who require institutional level care and who are Medicaid eligible.
- The community based, long term care waiver population - This includes individuals who are Medicaid eligible and are in need of community based long term care services to remain in their homes and avoid institutionalization.
- The Medicaid "community well" population - This represents the portion of the population who are not in need of long term care services and are living in the community.

1. Without Waiver Budget<sup>1</sup>

The institutional population has grown slowly for the last five years. The number of eligible member months has increased only 1.27% per year, but the cost per eligible has increased 16.69%, and total expenditures have increased sharply by more than 18% per year.

Prescription costs in this group have tracked the total expenditures, and are expected to represent about 5% of the total institutional costs. Total costs for institutional population during the demonstration project period is projected to be more than 1.8 billion dollars.

The home and community based waiver population has grown substantially. The number of eligible member months has increased 13.05% annually, but the cost per eligible has increased at a somewhat slower rate of 8.58%. Overall costs increased 22.74% per year.

Prescription costs in this group have increased at an overall rate of 29.3% per year, due in equal parts to the increases in the eligible member months and the average cost per eligible. Prescriptions for the waiver population are expected to make up about 17% of the projected \$890 million cost from SFY 04 to SFY 08.

The community well population has exhibited a moderate growth rate in eligible member months of 3.73% per year and has actually experienced a *decrease* in the overall cost per eligible of .61% per year. The cost of prescriptions for this group has increased about 19.4% annually, due in part to an increase in the cost per prescription per eligible. Since the overall cost per eligible is projected to decline slightly as the prescription cost per eligible increases, the pharmacy costs for this group will represent 44% of the total cost (\$780 million dollars) during the project period.

<sup>1</sup> Trends for pharmacy costs were generated by using the historical program data and the Pharmacy Plus budget template formulas.

2. With Waiver Budget<sup>1</sup>

a. The expansion group (the current DPAP population) is expected to grow at a moderate rate. The budget forecasts indicate that the eligible member months will increase at a rate of 8.95% and the cost per eligible will increase by 10.15% from SFY 04 to SFY 08. The projected gross total expenditure for the period is \$56,192,250. The following steps will be taken to reduce this projection:

- Manufacturer's rebates - Rebates of 15% are expected to be collected during the period. This will reduce the gross expenditures by \$8,428,838.

Waiver Yr.	1	2	3	4	5	Total
Exp's for Rx	\$7,549,847	\$9,060,453	\$10,873,307	\$13,048,884	\$15,659,760	\$56,192,251
Savings	\$1,132,477	\$1,359,068	\$1,630,996	\$1,957,333	\$2,348,964	\$8,428,838

- Retrospective review: Duplicate Therapies - An ongoing review of pharmacy claims indicates that 3% of all Medicaid prescriptions are duplicate therapies that occur in spite of the prospective DUR procedures. In these cases, pharmacists override the system's recommendations. The elimination of duplicate therapies would further reduce the expenditure level by \$1,685,768 over the demonstration period.

Waiver Yr.	1	2	3	4	5	Total
Exp's for Rx	\$7,549,847	\$9,060,453	\$10,873,307	\$13,048,884	\$15,659,760	\$56,192,251
Savings	\$226,495	\$271,814	\$326,199	\$391,467	\$469,793	\$1,685,768

The savings from these measures will reduce the total expenditures for the expansion group to \$46,077,645.

Waiver Yr.	1	2	3	4	5	Total
Exp's for Rx	\$7,549,847	\$9,060,453	\$10,873,307	\$13,048,884	\$15,659,760	\$56,192,251
Rebate	(\$1,132,477)	(\$1,359,068)	(\$1,630,996)	(\$1,957,333)	(\$2,348,964)	(\$8,428,838)
Dup Rx's	(\$226,495)	(\$271,814)	(\$326,199)	(\$391,467)	(\$469,793)	(\$1,685,768)
Balance	\$6,190,875	\$7,429,571	\$8,916,112	\$10,700,084	\$12,841,003	\$46,077,645

- b. New pharmacy benefit management procedures will also be applied to the existing elderly and disabled Medicaid populations to reduce pharmacy costs and achieve budget neutrality. Since these procedures will be applied to the institutional, waiver and community well populations, estimated cost reductions have been applied to aggregate expenditure projections for these groups.

- Step Therapy - EDS estimates that prescription costs for the Medicaid program will decrease by 5% after step therapy is implemented. This would produce savings of more than \$29.3 million dollars over the course of the demonstration project.

Waiver Yr.	1	2	3	4	5	Total
Exp's for Rx	\$77,752,649	\$93,681,929	\$113,023,985	\$136,547,860	\$165,295,077	\$586,211,500
Savings	\$3,887,632	\$4,684,096	\$5,651,199	\$6,827,393	\$8,260,254	\$29,310,575

- Retrospective review: Duplicate Therapies - The elimination of duplicate therapies in the existing Medicaid elderly and disabled populations would save 3% of prescription costs per year, or nearly \$17.5 million dollars over the course of the demonstration project.

Waiver Yr.	1	2	3	4	5	Total
3% of Rx's	22,371	23,244	24,150	25,092	26,071	
Av. Cost/Rx	\$104	\$121	\$140	\$162	\$188	
Savings	\$2,326,621	\$2,812,502	\$3,381,046	\$4,064,938	\$4,901,312	\$17,486,420

- Prospective DUR - Overutilization - EDS estimates that the number of prescriptions that are not filled as the result of overutilization could be increased by 25% per year. This would result in a savings of more than \$6.94 million dollars during the project period.

Waiver Yr.	1	2	3	4	5	Total
Savings	\$884,183	\$1,085,309	\$1,332,186	\$1,635,220	\$2,007,186	\$6,994,084

- Prior Authorization - A preliminary estimate indicates that \$ 4.1 million dollars could be saved by instituting prior authorization for the following: Provigil, Actiq, Renagel, 5HT3, Synagis, Duragesic, Cholinesterase Inhibitors, Oxycontin and Epoeitn.

Waiver Yr.	1	2	3	4	5	Total
Savings	595,571	690,266	800,019	927,222	1,074,650	\$ 4,087,727

### 3. Summary of Cost Effectiveness

For this Demonstration Project, total combined Medicaid expenditures for the elderly and disabled population groups would not exceed what the total Medicaid expenditures would be without the waiver. The savings attributable to the waiver would be realized by the application of new pharmacy benefit management procedures. The following table summarizes the total with and without waiver estimated expenditures over the five-year period.

Waiver Yr.	1	2	3	4	5	Total
Total WOW Expenditure	\$512,320,905	\$588,509,273	\$679,039,733	\$786,766,181	\$915,121,631	\$3,481,757,725
Less Step Therapy	(\$3,887,632)	(\$4,684,096)	(\$5,651,199)	(\$6,827,393)	(\$8,260,254)	(\$29,310,575)
Less Duplicate Therapy	(\$2,326,621)	(\$2,812,502)	(\$3,381,046)	(\$4,064,938)	(\$4,901,312)	(\$17,486,420)
Less Overutilization	(\$884,183)	(\$1,085,309)	(\$1,332,186)	(\$1,635,220)	(\$2,007,186)	(\$6,994,084)
Less Prior Authorization	(\$595,571)	(\$690,266)	(\$800,019)	(\$927,222)	(\$1,074,650)	(\$4,087,728)
New Expenditures	\$6,190,875	\$7,429,571	\$8,916,111	\$10,700,085	\$12,841,003	\$46,077,645
Total WW Expenditures	\$510,817,773	\$586,666,672	\$676,791,395	\$784,011,493	\$911,719,232	\$3,470,006,565
Savings	\$1,503,132	\$1,842,602	\$2,248,339	\$2,754,688	\$3,402,399	\$11,751,160

<sup>1</sup> Trends for pharmacy costs and savings were generated by using the historical program data and the Pharmacy Plus budget template formulas.

## VI. EXPENDITURE AUTHORITY

**The Following Authority is Needed for this Demonstration Under Costs not Otherwise Matchable** (item is checked to verify the request):

- A. \_\_\_\_\_ Section 1115(a)(1) authority of the Social Security Act is requested to enable the state to restrict freedom of choice of provider through a method such as pharmacy benefit management.
- B.   X   Section 1115(a)(2) authority of the Social Security Act is requested for the following expenditures to be made under the Delaware Pharmacy Assistance Program demonstration (which are not otherwise included as expenditures under section 1903) for the period of the demonstration to be regarded as expenditures under the Title XIX program.

Expenditures for extending pharmacy benefits for elderly and disabled individuals 19 to 64 years of age at or below 200 percent of the federal poverty level (FPL) who are Medicare eligible, or people with a disability, who are not otherwise Medicaid eligible under the state plan except for Medicaid coverage of Medicare premiums or cost sharing.

In addition, the following will not be applicable in this demonstration:

- *Premiums and Cost Sharing under Section 1916*: To permit fixed premiums, and cost sharing that is more than nominal, to be imposed on and collected from demonstration participants.
- *Amount Duration and Scope of Services under Section 1902(a)(10)(B)*: To permit the state to offer demonstration participants benefits that are not equal in amount, duration and scope to other Medicaid beneficiaries.
- *Retroactive Eligibility under Section 1902(a)(34)*: To permit the state not to offer demonstration participants retroactive eligibility.
- *Premiums under Section 1902(a)(14)*: To permit the state to impose on and collect premiums from demonstration participants in excess of those that would be permitted under section 1916.

## VII. EVALUATION

The purpose of Pharmacy Plus is to expand coverage of a prescription drug benefit to low-income seniors and Medicare beneficiaries with disabilities and, by so doing, to divert or defer entry by these individuals into the Medicaid program. Budget neutrality is a feature of these demonstrations and is designed to track the overall cost and savings of the program. However, it is important to evaluate these demonstrations in other than budgetary terms. To understand how effective the program is for individuals, provide a description below of the state context of the program, the goals for the program, and how the program's success will be evaluated. In addition, CMS intends to conduct an independent evaluation of several of the Pharmacy Plus demonstration projects.

Included as an Attachment to the Application are the following:

- A.   X   Current State Context. Provide an assessment of the current pharmacy coverage status of individuals in the state which includes summary information of individuals whose incomes are at or below 200 percent FPL who:
1.        do not have private insurance or other coverage of pharmaceuticals
  2.        have private insurance that covers pharmaceuticals
  3.   X   are in the state only funded pharmacy program: See attached program report
- B.   X   The state's goal for increasing pharmacy coverage to the population targeted by the demonstration, including:
1.   X   the state's demonstration hypothesis
  2.   X   the state's execution of the hypotheses via the demonstration project operation

Delaware proposes to achieve budget neutrality for elderly and disabled Medicaid populations by implementing new pharmacy benefit procedures. The following hypotheses will be tested:

- 1.) The proposed changes in pharmacy benefits management will indirectly reduce the hospitalization and institutionalization rates of the elderly and disabled Medicaid populations.

The accurate measurement of the health benefits associated with this demonstration is difficult and complex. Reliable data about the actual size of the eligible population is not available, there are no comparison groups to isolate the effects of particular pharmacy benefit changes, and we do not have access to Medicare data for the expansion population. Evaluation efforts will therefore be focused on before- and after- demonstration changes in the elderly and disabled populations.

Many pharmaceutical interventions are not cures. To be effective, individuals must follow the medication regimen for the rest of their lives. It could be argued that providing a pharmacy

benefit without proper management to insure patient compliance would lead to higher inpatient hospital and nursing home utilization rates, as well as higher costs for other home health/long-term care services.

This demonstration hypothesizes that changes in the management of the pharmacy benefit, in particular the reduction of overutilization and duplicate therapies, along with prior authorization for particular drug classes, will improve the health status of participants and indirectly reduce the use of inpatient hospital services, nursing home care and other medical services.

Existing elderly and disabled Medicaid populations - Data for pre- and post- demonstration inpatient hospital, nursing home utilization and other medical services for the existing elderly and disabled Medicaid populations will be monitored. To more accurately assess waiver outcomes, utilization rates will be collected for sub-populations and compared against projected rates of growth in each group.

Expansion population - Structured longitudinal interviews and/or surveys could be used to examine changes in health status and the utilization of healthcare services in the expansion population. Surveys or interviews and focus groups could also be used to aggregate information pertaining to perceived changes in quality of life and current and historic compliance with pharmaceutical regimens. Surveys or interview results would be used in conjunction with data from other sources to evaluate the success of the project.

Medicaid claims data for program participants will provide information regarding participant's demographics, prescriptions filled, total number of waiver participants and waiver expenditures.

Estimated cost savings from reduced inpatient hospitalization rates, nursing home admissions or emergency room visits, if any, will be calculated.

- 2.) Budget Neutrality - There will be no increase in the cost of Medicaid services for the elderly and disabled over what would have been expended in the absence of the new benefit.

It is expected that outlays incurred by providing pharmacy services to the expanded population will be offset by savings generated the implementation of new pharmacy benefit procedures.

Historical data and budget projections have been used to develop estimates of the overall cost and enrollment for the five years of the demonstration project. These include the total expected costs of Medicaid for the elderly and disabled without the demonstration and the total expected costs of Medicaid for the elderly, disabled and expanded populations with the demonstration.

The annual Medicaid expenditures and utilization for the demonstration will be monitored. These amounts will be compared on an on-going basis to the aggregate projections made at the inception of the program.



## VIII. ADDITIONAL REQUIREMENTS

In addition to the above requirements, the state agrees to the Pharmacy Plus Model Special Terms and Conditions (STCs) of Approval, and agrees to prepare the [Operational Protocol](#) document as described in the Model STCs. During CMS's review and consideration of this demonstration request, using the Model STCs, we will work with CMS to develop STCs that are specific to this request that would become part of the approval of demonstration authority.

This demonstration proposal is submitted to CMS on \_\_\_\_ - \_\_\_\_ - \_\_\_\_.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Authorizing Official, Typed

\_\_\_\_\_  
Name of Authorizing Official, Signed

# PHARMACY PLUS

## A DEMONSTRATION PROGRAM UNDER SECTION 1115

### Attachment 1

#### Public Notice ([Assurance D Description](#))

Provide a description of the public notice process for Pharmacy Plus, including varying activities and stakeholder groups included in each:

It is important to note that the Delaware Pharmacy Plus Waiver, as designed, will not reduce or affect in any way the prescription benefit or the eligible target group. The change should be invisible to the DPAP population. Therefore, the Public Notice process, while appropriate and necessary, will not need to be as extensive as might otherwise be the case where a program change is made involving a reduction of benefits, addition of benefits, restriction of freedom of choice, geographical limitations, etc.

However, if approved, the State will provide for Public Notice in the following manner:

- inform the Medicaid Medical Advisory Board
- inform the Medicaid Pharmacy Advisory Board
- publish public notice of the State Plan change for public comment
- inform all Medicaid providers via the Medicaid Newsletter including primary care providers, pharmacies, FQHCs, etc.
- inform the Tobacco Health Advisory Fund
- inform the State Health Care Commission
- inform the CHAP program
- inform sister agencies in State Government
- distribute CHAP materials to Pharmacies
- inform other interested groups and stakeholders as needed.

All public comments will be evaluated and considered as far as practical to efficiently administer the program under the terms of the Pharmacy Plus Waiver.

# PHARMACY PLUS

## A DEMONSTRATION PROGRAM UNDER SECTION 1115

### Attachment 2

### DEFINITIONS

**Budget Neutrality** –The policy for Section 1115 demonstrations under which the state does not receive more in federal title XIX matching funds under the demonstration than it would have received without it.

**Budget Neutrality Ceiling** –An expenditure limit, negotiated between the state and CMS, placed on the amount of FFP available to a state under the demonstration. The expenditure limit for Pharmacy Plus waivers is calculated using the aggregate method. The aggregate expenditure limit is calculated as a fixed amount that does not vary based upon enrollment changes in the state.

**Private Health Insurance** - Group health plan coverage and health insurance coverage as defined in section 2791 of the Public Health Services Act.

**Expansion population** - Individuals eligible for benefits under the state Pharmacy Plus demonstration program who are not enrolled in the regular Medicaid program.

**Full Medicaid benefit** – The Medicaid benefit package available to individuals who are eligible for Medicaid without the Pharmacy Plus waiver.

**Impacted population** - The Medicaid eligibility group or groups whose Medicaid costs are included in the budget neutrality cap. Under Pharmacy Plus, the state is expected to achieve savings from this group because of the diversion from the regular Medicaid program of a proportion of the expansion population.

**Enrollee Cost Sharing** – Premium charges, enrollment fees, deductibles, coinsurance, copayments or other similar fees that the Pharmacy Plus enrollee is responsible for paying. Cost sharing for Pharmacy Plus enrollees can deviate from requirements in Medicaid and can be used to reduce program costs by requiring participant payments, encouraging the use of non-brand drugs, and can vary to moderate out of pocket burdens for high utilizers.

**Enrollment Ceiling** -- A number limit on demonstration program enrollment. States may use an enrollment ceiling to limit the numbers of individuals enrolled in the demonstration so that financial risk for demonstration costs is minimized. States may not enact an enrollment ceiling for the non-demonstration Medicaid program.

**Drug Rebates** - The quarterly payments made by the pharmaceutical manufacturer to the state

Medicaid agency, as calculated in accordance with section 1927 of the Social Security Act and the provisions of the agreement between the manufacturer and the Secretary. States can receive rebates for pharmaceutical products in Pharmacy Plus as long as a state payment is made for the drug and there is not a formulary that does not conform to the provisions of 1927(d)(4) of the Act.

**Wraparound Coverage** - Pharmacy Plus coverage of services not covered under a beneficiary's private health insurance. Examples of wraparound coverage include a Pharmacy Plus program paying for drugs not covered by private insurance, a Pharmacy Plus program covering an amount of drugs in excess of that covered by private insurance (for example, if the private insurance coverage includes three prescriptions per month, Pharmacy Plus could pay for additional prescriptions); and Pharmacy Plus coverage when a private insurance financial benefit is exceeded.

**Terms and Conditions of Approval** - A document produced by CMS which provides conditions which states must follow in order to receive approval of their Pharmacy Plus waiver.

**Operational Protocol** - A stand-alone document that reflects the operating policies and administrative guidelines of the Pharmacy Plus waiver.

**Prior Authorization** – Requiring approval of the drug before it is dispensed for any medically accepted indication as defined in 1927(k)(6) of the Act.

**Formulary or Formulary Exclusions** - A list of prescription drugs developed in accordance with 1927(d)(4) of the Social Security Act. At state option, the formulary provisions for the expansion population may differ from 1927(d)(4) as delineated by the template allowance of coverage of condition-specific drugs or limited sets of drugs (see template).